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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/607,526	06/27/2003	Ronald J. Link	43738-0003CI (187273)	6041

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EXAMINER	
KOHUT, DAVID M	
ART UNIT	**PAPER NUMBER**
3626	
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07/17/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/607,526	LINK ET AL.	
	Examiner	Art Unit	
	David M. Kohut, Esq.	3626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 May 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-14* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-14* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *02 May 2007* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Amendment

1. In the amendment filed 2 May 2007, the following has occurred: claims 1 and 10-14 have been amended. In addition, changes to the specification and drawings have been noted.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

3. Claims 1-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Papageorge, U.S. Patent No. 6,584,445, reference A on the attached PTO-892, in view of Rakshit et al., U.S. Patent No. 5,799,282, reference B on the attached PTO-892.

4. As per claim 1, Papageorge teaches a computer implemented process for informing a patient of risks of undergoing a treatment, comprising: gathering semi-static data relating to contraindications to and complications associated with the treatment, i.e. while CHES consults medical experts as well, its outcome projections reflect statistically verified pattern differences in outcomes among treatments using many well-documented, published studies on treatment results to maximize the accuracy of the information provided and treatment, disease subcategories, concurrent conditions (related or unrelated), patient demographics, and any effect of recent medical advances in each treatment stratify the data from these studies (see column 7, lines 60-67 and

column 8, line 1 of Papageorge); gathering dynamic data relating to contraindications and complications that other patients experienced as a result of undergoing the treatment, said dynamic data comprising information abut the treatment conduct, its result, and the other patients' response over time, i.e. while CHES consults medical experts as well, its outcome projections reflect statistically verified pattern differences in outcomes among treatments using many well-documented, published studies on treatment results to maximize the accuracy of the information provided and treatment, disease subcategories, concurrent conditions (related or unrelated), patient demographics, and any effect of recent medical advances in each treatment stratify the data from these studies (see column 7, lines 60-67 and column 8, line 1 of Papageorge); from the gathered semi-static data and dynamic data, creating a rule-based algorithm for calculating the risks of the patient undergoing the treatment, i.e. these elements are then used to evaluate the costs, risks, and benefits of competing treatments (see column 8, lines 2-4 of Papageorge); acquiring relevant data of the patient, i.e. the patient then answers the questionnaire, using single keystrokes to select choices (see column 7, lines 1-2 of Papageorge); calculating a customized personal risk assessment for the patient, i.e. the report summarizes the data from the users, with conditional text on how each response affects the course of the disease and the probable results of each treatment option (see column 5, lines 44-47 of Papageorge); and presenting the customized personal risk assessment to the patient, i.e. the report summarizes the data from the users, with conditional text on how each response affects the course of the disease and the probable results of each treatment option (see column

5, lines 44-47 of Papageorge). However, Papageorge does not explicitly teach the process wherein the risk assessment is an informed consent form. Rakshit et al., however, does teach a process wherein the patient receives an informed consent form, i.e. the system will print an informed consent form, listing the key aspects of the interaction, complete with Patient A's name and a signature line, the date and time of consent, and such information (see column 14, lines 11-15 of Rakshit et al.). It would have been obvious to one of ordinary skill in the art at the time of the invention to incorporate this feature into the process of Papageorge. One of ordinary skill in the art would have been motivated to combine these features in order to properly understand the necessary aspects of the procedure to be performed (see column 3, lines 51-52 of Rakshit et al.).

5. As per claim 2, Papageorge and Rakshit et al. teach the process of claim 1 as described above. Papageorge further teaches the process wherein the step of creating a rule-based algorithm for calculating the risks of undergoing the treatment comprises: periodically updating both the semi-static data and dynamic data, i.e. CHES will have ongoing system updates to assure that they reflect the latest in medical knowledge and treatment technology to prevent the system from becoming obsolete (see column 9, lines 38-41 of Papageorge).

6. As per claim 3, Papageorge and Rakshit et al. teach the process of claim 1 as described above. Papageorge further teaches the process wherein the step of creating a rule-based algorithm for calculating the risks of undergoing the treatment comprises: recursively processing the rules governing the risk assessment relating to any treatment

based on periodic updates to one or both of the semi-static and dynamic data, i.e. CHES will have ongoing system updates to assure that they reflect the latest in medical knowledge and treatment technology to prevent the system from becoming obsolete (see column 9, lines 38-41 of Papageorge).

7. As per claim 4, Papageorge and Rakshit et al. teach the process of claim 1 as described above. Papageorge further teaches the process further comprising the step: formulating text material in the form of sentences that list risk factors and outcome information for display to the patient based on information gathered in the process, i.e. in creating the system conditional text would be written for each possible physician and patient questionnaire response, explaining its positive or negative impact on outcome (see column 9, lines 6-8 of Papageorge).

8. As per claim 5, Papageorge and Rakshit et al. teach the process of claim 4 as described above. Papageorge further teaches the process further comprising the step: creating a calculus that associates text sentences with the risk information to be presented to the patient, i.e. format a report showing the responses and conditional text, the patient's risk tolerance profile, patient and physician treatment preferences, how they compare to that found to be most cost-effective, and the factors supporting their choice (see column 9, lines 9-13 of Papageorge).

9. As per claim 6, Papageorge and Rakshit et al. teach the process of claim 1 as described above. Papageorge further teaches the process wherein the step of gathering dynamic data relating to experienced contraindications and complications associated with the treatment includes: identifying a particular treatment provider, and

incorporating data relating to the treatment provider, i.e. the users (patient, physician, and insurer) receive outcome data (morbidity and mortality rates) on each treatment and are told that these statistics are compiled from many published studies and must only be used to compare outcomes in their own geographic area (this resembles Prudential Insurance's program of paying patients' travel expenses to centers with the best outcomes on specific procedures) (see column 7, lines 25-32 of Papageorge).

10. As per claim 7, Papageorge and Rakshit et al. teach the process of claim 6 as described above. Papageorge further teaches the process wherein the step of incorporating data relating to the treatment provider further comprises: gathering and including data on the treatment provider's outcome history associated with the treatment, i.e. the users (patient, physician, and insurer) receive outcome data (morbidity and mortality rates) on each treatment and are told that these statistics are compiled from many published studies and must only be used to compare outcomes in their own geographic area (this resembles Prudential Insurance's program of paying patients' travel expenses to centers with the best outcomes on specific procedures) (see column 7, lines 25-32 of Papageorge).

11. As per claim 8, Papageorge and Rakshit et al. teach the process of claim 7 as described above. Papageorge further teaches the process wherein the step of incorporating data relating to the treatment provider further comprises: gathering and including data on the treatment provider's complication history in providing the subject treatment, i.e. the users (patient, physician, and insurer) receive outcome data (morbidity and mortality rates) on each treatment and are told that these statistics are

compiled from many published studies and must only be used to compare outcomes in their own geographic area (this resembles Prudential Insurance's program of paying patients' travel expenses to centers with the best outcomes on specific procedures) (see column 7, lines 25-32 of Papageorge).

12. As per claim 9, Papageorge and Rakshit et al. teach the process of claim 1 as described above. Rakshit et al. further teaches the process which includes gathering information about the pre-operative and post-operative care of the treatment provider's patients, i.e. this interactive process may continue for sections on the alternative choices to an abdominal hysterectomy, post-operative care, pre-operative preparation, etc. (see column 13, lines 57-59 of Rakshit et al.). It would have been prima facie obvious to one of ordinary skill in the art at the time of the invention to incorporate this feature into the method of Papageorge. One of ordinary skill in the art would have been motivated to incorporate this feature in order to help bridge the gaps that have existed between the legal, medical, consumer and training fields with respect to establishing certifiable informed consent (see column 4, lines 31-34 of Rakshit et al.).

13. As per claim 10, Papageorge teaches a computer-implemented process for informing a patient of risks of undergoing a treatment, comprising: gathering semi-static data relating to contraindications to and complications associated with the treatment, i.e. while CHES consults medical experts as well, its outcome projections reflect statistically verified pattern differences in outcomes among treatments using many well-documented, published studies on treatment results to maximize the accuracy of the information provided and treatment, disease subcategories, concurrent conditions

(related or unrelated), patient demographics, and any effect of recent medical advances in each treatment stratify the data from these studies (see column 7, lines 60-67 and column 8, line 1 of Papageorge); acquiring relevant data of the patient, i.e. the patient then answers the questionnaire, using single keystrokes to select choices (see column 7, lines 1-2 of Papageorge); calculating a customized personal risk assessment for the patient, i.e. the report summarizes the data from the users, with conditional text on how each response affects the course of the disease and the probable results of each treatment option (see column 5, lines 44-47 of Papageorge); and presenting the customized personal risk assessment to the patient, i.e. the report summarizes the data from the users, with conditional text on how each response affects the course of the disease and the probable results of each treatment option (see column 5, lines 44-47 of Papageorge). However, Papageorge does not explicitly teach the process wherein the customized personal risk assessment is an informed consent form. Rakshit et al., however, does teach a process wherein the patient receives an informed consent form, i.e. the system will print an informed consent form, listing the key aspects of the interaction, complete with Patient A's name and a signature line, the date and time of consent, and such information (see column 14, lines 11-15 of Rakshit et al.). It would have been obvious to one of ordinary skill in the art at the time of the invention to incorporate this feature into the process of Papageorge. One of ordinary skill in the art would have been motivated to combine these features in order to properly understand the necessary aspects of the procedure to be performed (see column 3, lines 51-52 of Rakshit et al.).

14. As per claim 11, Papageorge and Rakshit et al. teach the process of claim 10 as described above. Papageorge further teaches printing out the individualized risk assessment, i.e. the report informs physicians and patients of the costs, risks, and benefits of all treatment (see column 10, lines 5 and 8-9 of Papageorge). Additionally, Rakshit et al. further teaches the process wherein the presenting of the customized personal risk assessment to the patient further comprises printing the informed consent form, i.e. upon mastery of all objectives, the system will print an informed consent form, listing the key aspects of the interaction (see column 13, lines 63-64 of Rakshit et al.). It would have been prima facie obvious to one of ordinary skill in the art at the time of the invention to incorporate this feature into the process of Papageorge. One of ordinary skill in the art would have been motivated to incorporate this feature because using existing techniques, many non-emergency type surgical procedures require the patient to read and sign an "informed consent" form (see column 1, lines 32-34 of Rakshit et al.).

15. Claims 12-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Papageorge, U.S. Patent No. 6,584,445, reference A on the attached PTO-892, in view of Rakshit et al., U.S. Patent No. 5,799,282, reference B on the attached PTO-892, and Tyuluman et al., U.S. Patent No. 5,924,073, reference C on the attached PTO-892.

16. As per claim 12, Papageorge and Rakshit et al. teach the process of claim 10 as described above. Papageorge further teaches the process further comprising: gathering performance data including information on treatment outcomes a, i.e. the users (patient, physician, and insurer) receive outcome data (morbidity and mortality

rates) on each treatment and are told that these statistics are compiled from many published studies and must only be used to compare outcomes in their own geographic area (this resembles Prudential Insurance's program of paying patients' travel expenses to centers with the best outcomes on specific procedures) (see column 7, lines 25-32 of Papageorge). However, neither Papageorge nor Rakshit et al. teach the process wherein the performance data is specific to the provider's prior patients. Tyuluman et al., however, teaches a process wherein the performance data relates to a provider who performs the treatment including information on treatment outcomes after undergoing the treatment for other patients of the provider, i.e. the patient specific physician performance data may include information relating to a physician's ability to efficiently assess and treat an ailment (see column 8, lines 39-42 of Tyuluman et al.). It would have been prima facie obvious to one of ordinary skill in the art at the time of the invention to incorporate this feature into the processes of Papageorge and Rakshit et al. One of ordinary skill in the art would have been motivated to incorporate this feature in order to decide whether to seek medical treatment from a particular physician or health care provider (see column 11, lines 19-21 of Tyuluman et al.).

17. As per claim 13, Papageorge, Rakshit et al., and Tyuluman et al. teach the process of claim 12 as described above. Papageorge further teaches the process further comprising the step: from the gathered semi-static data, the patient data, and treatment provider data, creating a rule-based algorithm for calculating the risks of the patient undergoing the treatment, i.e. the computer system uses an algorithm for

weighing the patient data and the physician data in view of the database (see abstract, lines 9-11 of Papageorge).

18. As per claim 14, Papageorge, Rakshit et al., and Tyuluman et al. teach the process of claim 13 as described above. Papageorge further teaches the process further comprising the step of: recursively processing the rules governing the risk assessment relating to any treatment based on periodic updates to the semi-static data, the patient data, and provider data, i.e. CHES will have ongoing system updates to assure that they reflect the latest in medical knowledge and treatment technology to prevent the system from becoming obsolete (see column 9, lines 38-41 of Papageorge).

Response to Arguments

19. In the remarks filed 2 May 2007, Applicant argues that because of the way claims 1 and 10 were amended that (1) Papageorge does not describe a system that presents a customized personal risk assessment to the patient as an informed consent form; (2) Papageorge does not recite a process for informing a patient of the risks associated with a particular treatment that the patient is "undergoing" and has contemplated; (3) Papageorge does not use evolving data focused on risk reduction such as "other patients'" prior experiences "as a result of undergoing the treatment"; (4) since the independent claims (1 and 10) are allowable over Papageorge, so too are the dependent claims (2-9 and 11-14); (5) Rakshit et al., taken alone, does not describe the limitations of the process for informing a patient of the risks of undergoing a treatment and does not make up the shortcomings of the Papageorge reference; and (6) since the

independent claims (1 and 10) are allowable over Rakshit et al. and Papageorge, so too are the dependent claims (2-9 and 11-14).

20. In response to Applicant's argument (1), the Examiner has modified the rejection to include Rakshit et al. Rakshit et al. teaches the system wherein an informed consent document is presented to the patient, i.e. the system will print an informed consent form, listing the key aspects of the interaction (see column 14, lines 11-13 of Rakshit et al.). By combining the Rakshit et al. reference with Papageorge reference, which teaches an evaluation system for decision-making concerning the patient's specific disease or condition (see abstract of Papageorge), the claimed invention is taught. In addition, there is motivation to combine the two references to ensure that the patient properly understands the risks and necessary aspects of the procedure to be performed (see column 3, lines 51-52 of Rakshit et al.). Therefore, Examiner maintains the rejection of independent claims 1 and 10.

21. In response to Applicant's argument (2), the Examiner has modified the rejection to include Rakshit et al. Rakshit et al. teaches a process for informing a patient of the risks associated with a particular treatment that the patient is "undergoing" and has contemplated, i.e. the disclosed methods provide a reliable and effective means for certifying each patient's level of understanding with respect to information furnished on a pending medical procedure (see column 5, lines 19-22 of Rakshit et al.). In addition, there is motivation to combine the two references to ensure that the patient properly understands the risks and necessary aspects of the procedure to be performed (see

column 3, lines 51-52 of Rakshit et al.). Therefore, Examiner maintains the rejection of independent claims 1 and 10.

22. In response to Applicant's argument (3), the Examiner respectfully submits that Papageorge does in fact teach the use of evolving data focused on risk reduction such as "other patients'" prior experiences "as a result of undergoing the treatment", i.e. the users receive outcome data (morbidity and mortality rates) on each treatment and are told that these statistics are compiled from many published studies and must only be used to compare outcomes in their own geographic area (wherein the studies contain "other patients'" prior experiences "as a result of undergoing the treatment") (see column 7, lines 25-29 of Papageorge). Therefore, Examiner does not find any of Applicant's arguments regarding Papageorge to be persuasive.

23. In response to Applicant's argument (4), since Examiner has determined Applicant's arguments (1) – (3) to be unpersuasive, Examiner also finds Applicant's argument (4) to also be unpersuasive since it is founded upon the same reasoning.

24. In response to Applicant's argument (5), the Examiner respectfully submits that while the Rakshit et al. reference does not cover all limitations of the claimed invention, on its own, the reference does in fact cover all of the limitations in combination with the Papageorge reference. As such, independent claims 1 and 10 are appropriately rejected under 35 U.S.C. § 103(a) which allows the combination of references to reject a claim. Therefore, Examiner does not find any of Applicant's arguments regarding Papageorge in view of Rakshit et al. to be persuasive.

25. In response to Applicant's argument (6), since Examiner has determined Applicant's argument (5) to be unpersuasive, Examiner also finds Applicant's argument (6) to also be unpersuasive since it is founded upon the same reasoning.

Conclusion

1. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

2. A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

3. Any inquiry concerning this communication or earlier communications from the Examiner should be directed to David M. Kohut, Esq. whose telephone number is 571-270-1369. The Examiner can normally be reached M-Th 730-5 w/1st Fri off. 2nd Fri 730-4.

4. If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Joseph Thomas can be reached at 571-272-6776. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

5. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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